

IN THE CLAIMS:

Claim 20 was previously cancelled. Claims 1-14, 17-19, and 21 have been amended herein. New claims 22 through 26 are presented herein. All of the pending claims 1-19 and 21-25 are presented below. This listing of claims will replace all prior versions and listings of claims in the application. Please enter these claims as amended.

Listing of the Claims:

1. (Currently Amended) A pharmaceutical composition, wherein the pharmaceutical composition:

comprises a polytartrate polymer and at least one pharmaceutically active material,

is capable of releasing the pharmaceutically active material in a pulsatile manner when the composition is administered to a human or ~~other~~ animal, and

is in the form of a tablet prepared with a tablet press using a compression force of from 10 to 65 kN/cm²;

wherein the pharmaceutical composition does not comprise a barrier structure.

2. (Currently Amended) The ~~composition according to claim 1~~ process according to claim 14, wherein the compression force in the ~~tablet press~~ tableting equipment is from 20 to 50 kN/cm².

3. (Currently Amended) The pharmaceutical composition according to claim 1, wherein the polytartrate polymer forms degradation products that increase the pressure inside the pharmaceutical composition when the pharmaceutical composition is administered to a human or ~~other~~ animal.

4. (Currently Amended) The pharmaceutical composition according to claim 3, wherein the degradation products comprise at least one compound selected from the group consisting of a C1 to C4 alcohol, aldehyde, ester, and acetone.

5. (Currently Amended) The pharmaceutical composition according to claim 4, wherein the degradation products comprise at least one compound selected from the group consisting of methanol, ethanol, propanol, isopropanol, and acetone.

6. (Currently Amended) The pharmaceutical composition according to claim 1, wherein the polytartrate polymer is a polycondensate of:

dimethyl tartrate, diethyl tartrate, diisopropyl tartrate, or one or more copolymers of at least two of dimethyl tartrate, diethyl tartrate, and diisopropyl tartrate; and
one or more 2,3-O-alkylidenetartaric acid derivatives.

7. (Currently Amended) The pharmaceutical composition according to claim 6, wherein the polytartrate polymer is 2'3'-(1',4'-diethyl)-L-tartryl poly-(2,3-O-isopropylidene)-L-tartrate.

8. (Currently Amended) The pharmaceutical composition according to the claim 1, wherein the polytartrate polymer has a glass transition temperature that is greater than 40° C.

9. (Currently Amended) The pharmaceutical composition according to claim 1, wherein the pharmaceutically active material comprises at least one material selected from the group consisting of antigens, antibodies, and pharmaceutical substances.

10. (Currently Amended) The pharmaceutical composition according to claim 9, wherein the pharmaceutically active material is a GnRH agonist.

11. (Currently Amended) The pharmaceutical composition according to claim 10, wherein the pharmaceutically active material is buserelin.

12. (Currently Amended) The pharmaceutical composition according to claim 10, wherein the pharmaceutically active material is azagly nafarelin.

13. (Currently Amended) The pharmaceutical composition according to claim 1, wherein the tablet additionally comprises one or more pharmaceutically acceptable excipients or adjuvants.

14. (Currently Amended) A process for preparing ~~a polytartrate~~ the pharmaceutical composition according to claim 1, wherein the process comprises:

a) mixing an effective amount of a pharmaceutically active material with a polytartrate polymer, and

b) shaping the mixture with tableting equipment to form a compressed tablets tablet by applying a compression force of from 10 to 65 kN/cm²;

wherein the compressed tablet is capable of releasing the pharmaceutically active material in a pulsatile manner when the pharmaceutical composition is administered to a human or animal; and

wherein the compressed tablet does not comprise a barrier structure.

15. (Previously Presented) The process according to claim 14, wherein the pharmaceutically active material and the polytartrate polymer are mixed in a powdered form.

16. (Previously Presented) The process according to claim 14, wherein the mixture is sieved.

17. (Currently Amended) A method of administering a pulsatile pharmaceutically active material to a human or ~~ether~~ animal, wherein the method comprises administering the pharmaceutical composition of Claim 1 to the human or ~~ether~~ animal.

18. (Currently Amended) The method of Claim 17, wherein the method comprises administering the pharmaceutical composition ~~of Claim 1~~ to a human.

19. (Currently Amended) A method of administering a pharmaceutically active material to a human or ~~other~~ animal, wherein:

the method comprises administering [[a]] the pharmaceutical composition of Claim 1 to the human or ~~other~~ animal, and

a majority of the pharmaceutically active material is released in an initial burst and a second burst.

20. (Canceled).

21. (Currently Amended) The method of Claim 17, wherein the method comprises administering the pharmaceutical composition of ~~Claim 1~~ to a non-human animal.

22. (New) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is capable of releasing the pharmaceutically active material in a triphasic manner when the composition is administered to a human or ~~other~~ animal.

23. (New) The pharmaceutical composition of claim 22, wherein the triphasic matter comprises an initial burst phase, a lag phase, and a second burst phase.

24. (New) A pharmaceutical composition, wherein the pharmaceutical composition: consists essentially of a polytartrate polymer, at least one pharmaceutically active material, and one or more pharmaceutically acceptable excipients or adjuvants and releases the pharmaceutically active material in a pulsatile manner when the pharmaceutical composition is orally administered to a human or animal.

25. (New) The pharmaceutical composition of claim 26, wherein the pharmaceutical composition consists essentially of a polytartrate polymer and at least one pharmaceutically active material.

26. (New) A tablet for administering a pharmaceutically active material to a human or animal, said tablet prepared with tableting equipment using a compression force of from 10 to 65 kN/cm², which tablet does not comprise a barrier structure, the tablet comprising:

a polytartrate polymer that forms degradation products in the tablet that increase pressure inside the tablet, the degradation products comprising at least one compound selected from the group consisting of a C₁ to C₄ alcohol, aldehyde, ester, and acetone, and

at least one pharmaceutically active material,

wherein the tablet releases pharmaceutically active material in a pulsatile manner after administration to the human or animal.